

REMARKS

**I. Comments on Restriction Requirement**

Claim 8 is a method of making the polypeptides of Group I, and Claims 18, 44, 45, and 46 are methods of using the polypeptides of Group I, which should be examined together with the polypeptides of Group I, per the Commissioner's Notice in the Official Gazette of March 26, 1996, entitled "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)" which sets forth the rules, upon allowance of product claims, for rejoinder of process claims covering the same scope of products.

**II. Comments on the Rejection of Claims 1-2 and 15-16 Under 35 U.S.C. § 101**

The claimed polypeptides and compositions have utility as also explained in the Response filed January 29, 2003 (those comments being incorporated herein).

Furthermore, the rejection under 35 U.S.C. § 101 as made in the Final Office Action contains statements in at least six locations on three pages that appear to reference patent applications other than the instant application.

On page 4, the Examiner states that "Applicant argues that use of the claimed polypeptides for diagnosis of conditions or diseases characterized by expression of **RBTNH** for toxicology testing, and for drug discovery are sufficient utilities under 35 USC 101 and 112, first paragraph and that there is a 'well-established' use for the claimed invention, specific practical and beneficial uses for the invention, and that those uses are substantial." (emphasis added.) Applicants note that the instant application does not recite "RBTNH."

On page 7, the Examiner states that "[f]urther, since the specification does not establish that the protein of SEQ ID NO:1 is expressed in any **eating disorder** in any way that is different from the way it is expressed in normal individuals." (emphasis added.) Applicants note that the instant application does not recite "eating disorder."

On page 7, the Examiner states that "[f]inally, Declarant asserts that one would use ELISA, RIA or FACS for measuring **NHT**, and thus that the protein has utility. This argument has been fully considered but is not deemed persuasive because such analysis, in the absence of any known role of

NHT, is considered to be further research on NHT itself, to determine the role, function and properties of the protein.” (emphasis added.) Applicants note that neither the Furness Declaration nor the instant application recite “NHT.”

On pages 9-10, the Examiner states that “[t]here is no evidence of record or any line of reasoning that would support a conclusion that the HTAP protein of the instant application was, as of the filing date, useful for **diagnosis, prevention and treatment of diseases related to dysregulated cell growth and proliferation, including cancer** as stated at page 1 of the specification.” (emphasis added.) Applicants note that the instant application states on page 1:

This invention relates to nucleic acid and amino acid sequences of a novel tumorigenesis protein and to the use of these sequences in the **diagnosis, prevention, and treatment of disorders associated with cell proliferation and inflammation.** (emphasis added.)

Applicants assume that the cited statements in the Final Office Action were inadvertent.

**III. Comments on the Rejection of Claims 1-2 and 15-16 Under 35 U.S.C. § 112, first paragraph, enablement, and the Rejection of Claims 1 and 15 Under 35 U.S.C. § 112, first paragraph, written description**

The claimed polypeptides and compositions are adequately enabled and have adequate written description as also explained in the Response filed January 29, 2003 (those comments being incorporated herein).

CONCLUSION

In light of the above remarks, Applicants submit that the present application is fully in condition for allowance, and request that the Examiner withdraw the outstanding rejections. Early notice to that effect is earnestly solicited.

If the Examiner contemplates other action, or if a telephone conference would expedite allowance of the claims, Applicants invite the Examiner to contact Applicants' Attorney/Agent below.

If the USPTO determines that any additional fees are due, the Commissioner is hereby authorized to charge Deposit Account No. **09-0108**.

Respectfully submitted,  
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